IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 20-738-CMR

ORDER

AND NOW, this _____ day of _____, 2020, upon consideration of the Motions for Summary Judgment filed by each party and any responses thereto, it is ORDERED that:

(1) Defendant's motion is GRANTED;

(2) Plaintiffs' motion is DENIED;

(3) Pursuant to 42 U.S.C. § 405(g) (made applicable by 42 U.S.C. § 1395ii), judgments are entered affirming the following decisions of Defendant, Alex M. Azar, II, Secretary of the U.S. Department of Health and Human Services:

a. the unfavorable decision in Office of Medicare Hearings and Appeals ("OMHA") Appeal Number 1-8411344383 against Plaintiff Ronald Lewis, dated May 30, 2019; and

b. the unfavorable decision in OMHA Appeal Number 1-8393258352 against Plaintiff Lynn Oxenberg, dated September 5, 2019; and

(4) The Clerk of the Court shall enter the foregoing judgments and mark this case CLOSED.

BY THE COURT:

HONORABLE CYNTHIA M. RUFE
Judge, United States District Court

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 20-738-CMR

DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

Defendant Alex M. Azar, II, Secretary of the U.S. Department of Health and Human Services (the "Secretary"), moves this Court pursuant to 42 U.S.C. § 405(g) (made applicable by 42 U.S.C. § 1395ii), Fed. R. Civ. P. 56(a), and the Court's April 3, 2020 Order [Dkt. 14] to enter summary judgment for the Secretary. Additionally, the Court should deny the Motion for Summary Judgment filed by Plaintiffs Lynn Oxenberg and Ronald Lewis [Dkt. 12] on March 30, 2020.

As grounds for this cross-motion, the Court is referred to the following materials filed in support of the motion:

a. the Secretary's brief in support of this motion;

b. the Secretary's answer to the complaint; and

c. the certified Administrative Record.

Respectfully submitted,

WILLIAM M. McSWAIN
United States Attorney

/s/ Susan R. Becker
for Gregory B. David
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney/
Assistant Regional Counsel, HHS
Eric.Wolfish@hhs.gov

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
Tel: 215-861-8335
Fax: 215-861-8618
Matthew.Howatt@usdoj.gov

Dated: April 20, 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services, *Defendant*.	Civil Action No. 20-738-CMR

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF HIS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I. INTRODUCTION

Plaintiffs Lynn Oxenberg and Ronald Lewis are suffering from a terrible and deadly form of brain cancer, glioblastoma multiforme ("GBM"). This case involves judicial review of the denial of two Medicare claims, one for each Plaintiff, for certain months of tumor treatment field therapy ("TTFT") to treat GBM. [1] Plaintiffs raise a single issue on appeal: whether the Secretary of the Department of Health and Human Services (the "Secretary") is *forever* collaterally estopped from denying Plaintiffs' TTFT claims because an administrative law judge ("ALJ") allowed coverage for certain months of TTFT claims. But Plaintiffs are simply wrong on the law: there is no collateral estoppel here.

The United States cannot be estopped on the same terms as a private litigant, and the Supreme Court has never upheld an assertion of offensive collateral estoppel against the United States. *Heckler v. Community Health Servs. Of Crawford Co., Inc.*, 467 U.S. 51, 60 (1984); *United States v. Mendoza*, 464 U.S. 154, 159-60 (1984). Although Plaintiffs assert offensive collateral estoppel against the Secretary, they admit that Medicare ALJ decisions have "no precedential effect." Certified Administrative Record ("CAR") at 55. Plaintiffs' admission is consistent with the applicable Medicare statute and regulations, which prohibit ALJ decisions from having any preclusive effect in future cases. *See, e.g.*, 42 U.S.C. § 1395ff(d)(2)(B); 42 C.F.R. § 405.1062(b).

Indeed, the case that Plaintiffs principally rely upon in support of collateral estoppel held that preclusion cannot apply when there is a statutory purpose to the contrary, as there is here. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991). Giving preclusive

---

[1] Plaintiffs are not financially responsible for paying for the TTFT claims at issue if Medicare does not cover it. *See infra* § II.F.

effect to ALJ decisions would also interfere with the Secretary's discretion to permit case-by-case adjudication of Medicare claims. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984). While Plaintiffs fail to cite any cases on point, the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have followed the Supreme Court's reasoning and rejected similar attempts to bind federal agencies to non-precedential decisions in administrative appeals. *See infra* § IV.B.2.

The Court should reject Plaintiffs' assertion of collateral estoppel for five additional reasons. First, the Medicare statute's presentment and channeling requirements bar Plaintiffs' attempt to circumvent the administrative appeals process by seeking a judicial determination that the Secretary must cover future claims. 42 U.S.C. § 405(g), (h); *Ringer*, 466 U.S. at 620-21; *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000); *Porzecanski v. Azar*, 943 F.3d 472, 483 (D.C. Cir. 2019). Second, the Appropriations Clause of the Constitution prohibits estoppel claims for the payment of money from the federal government. Art. I, § 9, cl. 7; *Office of Personnel Management v. Richmond*, 496 U.S. 414, 424-25 (1990). Third, the elements of collateral estoppel are not present here. Notably, Plaintiffs' claim appeals involved different issues. The ALJs who approved Plaintiffs' claims expressly limited their holdings to certain months of TTFT treatment and *never* decided whether future claims for treatment should be allowed. Plaintiff Lewis cannot assert collateral estoppel because the "unfavorable" decision at issue in this case pre-dates his only "favorable" decision. *See infra* § IV.A. In addition, the Secretary did not have a full and fair opportunity to litigate Plaintiffs' appeals.

Fourth, fairness is an essential element for the application of offensive collateral estoppel. It is impracticable for the Secretary to appear as a party in the *over 400,000* Medicare claim

appeals that are filed each year at the ALJ level.[2] It would therefore be unfair to conclude that the Secretary has opened the door to collateral estoppel. A finding that favorable ALJ decisions collaterally estop the Secretary would also have widespread, negative ramifications for the Secretary and Medicare beneficiaries. The Secretary would be forced to devote Medicare resources to actively litigate hundreds of thousands of ALJ appeals to avoid the risk of collateral estoppel, thereby taking resources away from tens of millions Medicare beneficiaries.

Finally, collateral estoppel does not apply when the controlling legal principles or facts have significantly changed. *Montana v. United States*, 440 U.S. 147, 155 (1979). The Local Coverage Determination ("LCD") in effect at the time of the unfavorable decisions categorically denied Medicare coverage for TTFT. A new LCD that became effective on September 1, 2019 allows TTFT coverage in certain circumstances (the "2019 LCD"). Because the controlling legal principle underlying the unfavorable decision has significantly changed, if collateral estoppel were legally supportable – which it is not – it could not be applied after the issuance of the 2019 LCD.

Because the application of collateral estoppel to ALJ decisions is contrary to the Constitution, the Medicare statute and regulations, Supreme Court precedent, and numerous circuit-level decisions, summary judgment should be granted in the Secretary's favor and Plaintiffs' motion for summary judgment should be denied.[3]

---

[2] *See* U.S. Government Accountability Office Report at 1, 12 (May 2016), https://www.gao.gov/assets/680/677034.pdf (last visited April 17, 2020); *also* 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016).

[3] Plaintiffs' summary judgment motion abandons any arguments other than collateral estoppel. *See* Plaintiffs' summary judgment brief [Dkt. 12] (Pl. Br.) at 1-3, 10 (raising only collateral estoppel). Because Plaintiffs' have abandoned any other grounds to challenge the ALJ decisions at issue, the Secretary does not address them.

II. STATUTORY AND REGULATORY BACKGROUND

A. "Reasonable and Necessary" Medicare Expenses

Medicare is a federal health insurance program for people who are elderly and/or have disabilities. *See* 42 U.S.C. § 1395. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute. *Id*.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). The various benefit categories available under Medicare Part B are set forth in 42 C.F.R. part 410. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage. Under this section, "no payment may be made under . . . part B of this subchapter for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A). Unless there is an exception, this bar applies "[n]othwithstanding any other provision" of the Medicare statute. 42 U.S.C. § 1395y(a)(1)(A). The Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare program for the Secretary, has historically interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual ("MPIM") § 13.5.4.[4]

[4] The MPIM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf. The MPIM "is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment." *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

To administer the "reasonable and necessary" standard, the Secretary employs a range of tools, from formal regulations to informal manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, "either by default rule or by specification, address every conceivable question" that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate "reasonable and necessary" standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the "Reasonable and Necessary" Standard Through Local Coverage Determinations ("LCDs")

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services.[5] CMS, in turn, contracts with Medicare Administrative Contractors ("MACs"), such as Noridian Healthcare Solutions in this case, to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. Consistent with controlling regulations and NCDs, a MAC makes coverage determinations, issues payments, and develops LCDs for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the contractor that issued it, and

[5] *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f).

only at the initial stages of the Medicare claim review process, as opposed to later stages if a claimant should appeal a determination by a MAC. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, such as the one at issue in this case, MACs follow guidance contained in the MPIM. The MPIM requires MACs to publish LCDs that specify when "an item or service is considered to be reasonable and necessary." MPIM § 13.5.4. MACs develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1, 13.5.3, 13.5.5; 66 Fed. Reg. 58,788, 58,788 (Nov. 23, 2001). MACs also follow detailed procedures for issuing new or substantively revised LCDs, including engaging in a comment-and-notice period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

C. The Process of Promulgating LCDs

New LCDs require both a notice period and a comment period. MPIM § 13.2.4.2. The MAC first issues a draft LCD and provides the public a minimum of 45 days to comment on it. LCDs are principally based upon "available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines." MPIM § 13.5.3. After considering all of the comments and revising the LCD as needed, the contractor publishes the final LCD, providing at least a 45-day notice period before the LCD goes into effect. *Id*. at § 13.2.6.

D. The LCD for TTFT Devices

In April 2011, the United States Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune) manufactured and supplied to

beneficiaries by Novocure, for the treatment of recurrent GBM. CAR at 141.[6] Following an open meeting and solicitation of public comments, in August 2014, the DME MACs issued the original LCD for TTFT. *Id.* "The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM." *Id.* The LCD in effect at the relevant time, *i.e.*, during the dates of service for the claims on appeal, remained substantively unchanged and stated that "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." CAR at 13.

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. CAR at 141. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. CAR at 136-37. Novocure was "extremely pleased" with the 2019 LCD and notes that its coverage criteria "is generally similar to Optune's commercial coverage criteria for newly diagnosed GBM."[7]

E. Claims and Administrative Appeals

In order for a beneficiary to challenge a denial of a claim under the Medicare statute, he or she must submit a claim for payment to the Medicare contractor, and if the claim is denied, the beneficiary must generally exhaust the following four levels of administrative review before filing suit in district court. *See generally* 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the

---

[6] Plaintiff Oxenberg cited the 2019 LCD in her appeal (CAR at 108, 132-53), which is also available at: https://med.noridianmedicare.com/documents/2230703/7218263/Tumor+Treatment+Field+Therapy+%28TTFT%29%20LCD+and+PA/8f195ce1-c8e1-4c92-8578-f2b8996e4507 (last visited April17, 2020).

[7] *See* Medicare Releases Final Local Coverage Determination Providing Coverage of Optune® for Newly Diagnosed Glioblastoma, https://www.novocure.com/medicare-releases-final-local-coverage-determination-providing-coverage-of-optune-for-newly-diagnosed-glioblastoma/ (last visited April 17, 2020).

beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. At the second level, a beneficiary may seek reconsideration by a qualified independent contractor ("QIC") whose panel members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). An LCD is not binding at this and at higher levels of appeal. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). At the third level, a beneficiary can request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ's decision by the Medicare Appeals Council (the "Council"), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. The Council's decision (or the ALJ decision, if not reviewed by the Council) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

The claimant is entitled to judicial review of the Secretary's decision in the district court "as is provided in [42 U.S.C.] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). In such review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

F. Advanced Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b). As the ALJs found, because Novocure did not require Plaintiffs to sign an Advance Beneficiary Notice, no matter the outcome of this case, they will not be financially responsible for the TTFT claims at issue. *See* CAR at 109, 839.

G. Plaintiffs' Claims and Administrative Exhaustion

This case arises from the denial of Plaintiffs' claims for Medicare coverage of certain months of treatment with the Optune system for their GBM. Compl. [Dkt. 1] ¶¶ 21, 27. Plaintiffs have fully exhausted their administrative remedies, because the ALJ decisions denying their claims became final when the Council did not timely respond to their notices of escalation. *Id.* ¶ 5. Plaintiffs filed the instant action instead of seeking a hearing before the Council. CAR at 1-2, 726-27.

III. STANDARD OF REVIEW

Even though cross-motions for summary judgment are before the Court, the standard articulated in Federal Rule of Civil Procedure 56 is inapplicable because the Court has a more limited role in reviewing the administrative record. *Uddin v. Mayorkas*, 862 F. Supp. 2d 391, 399 (E.D. Pa. 2012); *Wilhelmus v. Geren*, 796 F. Supp. 2d 157, 160 (D.D.C. 2011). Instead, summary judgment is the "mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard

of review." *La. Forestry Ass'n, Inc. v. Solis*, 889 F. Supp. 2d 711, 720 (E.D. Pa. 2012) (quoting *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006)), *aff'd sub nom. La. Forestry Ass'n Inc. v. Sec'y U.S. Dep't of Labor*, 745 F.3d 653 (3d Cir. 2014).

For appeals arising under section 405(g), a court must uphold an ALJ's findings if they are supported by substantial evidence. *See McGinnis v. Social Security Admin.*, 2020 WL 1623703, at *2 (3d Cir. Apr. 2, 2020); *Rutherford v. Barnhart*, 399 F.3d 546, 552 (3d Cir. 2005). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Rutherford*, 399 F.3d at 552 (citation omitted). It is "more than a mere scintilla but may be somewhat less than a preponderance of the evidence." *Id*. (citation omitted).

IV. ARGUMENT

A. Plaintiffs' Irrelevant Evidence and Argument Outside of the Administrative Record Should be Excluded

As a threshold matter, the Court's decision in this claim appeal must be based *only* upon the certified administrative record. Plaintiffs concede that judicial review in this case is authorized by 42 U.S.C. § 405(g) (made applicable to the Secretary by 42 U.S.C. 1395ii), *see* Compl. at ¶ 5, Pl. Br. at 10, which says in the relevant part:

> As part of the [Secretary]'s answer the [Secretary] shall file a certified copy of the transcript of the record including the evidence upon which the finding and decision complained of are based. The court shall have power to enter, *upon the pleadings and transcript of the record*, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

(emphasis added). Accordingly, Plaintiffs' proffered evidence and argument that is outside of the administrative record is not properly within the scope of this appeal and should be excluded from the Court's consideration of this case. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) ("[t]he grounds upon which an administrative order must be judged are those upon which the

record discloses that its action was based."); *Fargnoli v. Massanari*, 247 F.3d 34, 44 n.7 (3d Cir. 2001) (applying *Chenery* in cases arising under section 405(g)); *Jones v. Soc. Sec. Admin.*, 2018 WL 5817351, at *4 (D.D.C. Nov. 7, 2018) ("[T]he Court's review is confined to the administrative record that was before the ALJ at the time of the decision[.]"); *Debaise v. Astrue*, 2010 WL 597488, at *14 (W.D. Pa. Feb. 16, 2010) ("[T]he Court cannot undertake a de novo review of the Commissioner's decision or consider evidence outside the record.").

Plaintiff Lewis' unfavorable decision on appeal is dated May 30, 2019. The court should exclude Lewis' *subsequent* favorable decision, dated October 24, 2019. *See* Ex. F to Pl. Br. Because the favorable decision was issued months *after* the unfavorable decision, it was not part of the administrative record. *See* CAR at 833-844 (5/30/19 ALJ Decision), 849 (ALJ Exhibit List). Collateral estoppel cannot apply as to Plaintiff Lewis, because the unfavorable decision on appeal *predates* his favorable ALJ decision. *See* Pl. Br. at 2 (asserting that an earlier-decided case may have preclusive effect). Therefore, because Plaintiff Lewis has appealed only on collateral estoppel grounds, the Court should grant summary judgment in the Secretary's favor.[8]

Likewise, the unfavorable decision Plaintiff Oxenberg presents on appeal is dated September 5, 2019. Accordingly, the Court should exclude her simultaneous or subsequent favorable decisions, dated September 5, 2019 and October 24, 2019. *See* Exs. B, C to Pl. Br. Plaintiff Oxenberg did not identify these decisions in the Complaint; the decisions were not in the record before the ALJ who rendered the decision; and they are irrelevant to Plaintiff Oxenberg's collateral estoppel argument. *See* CAR at 103-114 (9/5/19 ALJ Decision), 115 (ALJ Exhibit List).

[8] Indeed, the timing of the ALJ decisions alone disposes of Plaintiff Lewis' claim. Unless specifically noted, the following arguments apply to both Plaintiffs' claims. However, the Court need not reach them as to Plaintiff Lewis.

In addition, Plaintiffs' brief contains a number of gratuitous assertions for which they give no evidentiary support and, in any event, are far outside the administrative record and the scope of the issues on appeal in this case. Pl. Br. at 6 (personal facts regarding Plaintiff Oxenberg), 9 (personal facts regarding Plaintiff Lewis), 13-14 ("Response to the Secretary's Comments Regarding Coverage and Financial Responsibility"). In particular, Plaintiffs have not introduced any evidence concerning the status of their recent TTFT claims. Novocure is not a party to this federal court appeal and there is no evidence Novocure has required Plaintiffs to sign Advance Beneficiary Notices in order to continue receiving treatment, or is even considering that possibility. Each of these issues would require discovery, which the parties agree is unnecessary in an administrative record review case such as this. *See* Report of Rule 26(f) Meeting [Dkt. No. 11] at 2 ("As this case can be decided on administrative records, no discovery is necessary."). Regardless, Plaintiffs' arguments in this regard are irrelevant and the Court should disregard them.[9]

B. The Common Law Doctrine of Collateral Estoppel is Inapplicable in Medicare Claim Appeals

1. ALJ Decisions expressly do not bind the Secretary in future cases.

Although Plaintiffs primarily base their collateral estoppel argument on a passage from the U.S. Supreme Court decision in *Astoria*, Pl. Br. at 2-3,[10] they tellingly omit the very next

---

[9] To the extent that issues about Plaintiffs' current health status arose during status conferences, they were in response to the Court's concerns about how that should affect scheduling.

[10] In *Astoria*, the Court considered whether claimants alleging age discrimination under federal law are "collaterally estopped to re-litigate in federal court the judicially unreviewed findings of a state administrative agency made with respect to an age-discrimination claim." 501 U.S. at 106. The Court held that the state court's findings had no preclusive effect on federal proceedings. *Id.* Because the federal government was not a party, and the Court found the *absence* of estoppel, Plaintiffs' cited language is mere dicta.

paragraph, which explains that preclusion cannot apply when there is a statutory purpose to the contrary: "Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand[,] ... [and] the question is not whether administrative estoppel is wise but whether it is intended by the legislature." 501 U.S. at 108. The Third Circuit has also held that collateral estoppel may not be applied if it would "frustrate congressional intent or impede the effective functioning of the agency." *Duvall v. Atty. Gen. of U.S.*, 436 F.3d 382, 387-88 (3d Cir. 2006) (citing *Astoria* at 108-11). Here, the Medicare statute and regulations clearly bar the application of collateral estoppel to ALJ decisions.[11]

The Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of non-precedential decisions that are not binding. Only Council-level decisions have the potential to become precedential, which occurs only if they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. Council decisions designated as precedential must be made available to the public, with personally identifiable information removed, and notice of precedential decisions must be published in the Federal Register. 42 C.F.R. § 401.109(b). That decision is then given "precedential effect" and is binding on "all HHS components that adjudicate matters under the jurisdiction of CMS." *Id.* § 401.109(c).[12] The term "precedential effect" means that the Council's:

> (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

---

[11] Plaintiffs' reliance on *B & B Hardware, Inc. v. Hargis Indus., Inc.*, is also misplaced, Pl. Br. at 3, because the case involved private parties, and the Court did not consider whether the federal government may be bound by administrative decisions. 575 U.S. 138 (2015).

[12] HHS is the United States Department of Health and Human Services.

> (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term "precedential effect" is synonymous with a decision having binding or preclusive effect.

It is undisputed that no Council decision, much less one designated as precedential, has favorably decided Plaintiffs' claims. Accordingly, nothing in the Medicare statute or regulations binds the Secretary to approve Plaintiff's TTFT treatment. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions finding that the device at issue was "reasonable and necessary" or "safe and effective").

Instead, Plaintiffs' collateral estoppel argument relies upon a favorable ALJ decision that departed from the LCD and approved TTFT treatment.[13] However, an ALJ's decision to depart from an LCD "applies only to the specific claim being considered and does not have precedential effect." 42 C.F.R. § 405.1062(b) (emphasis added); 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005) ("[T]he ALJ or [Council] may decline to follow a policy in a particular case, but must explain the reason why the policy was not followed. These decisions apply only for purposes of the appeal in question, and do not have precedential effect."). The regulations re-affirm that only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . . ." 42 C.F.R. § 405.1063(c). "Nowhere does any policy or regulation suggest that the [Council] owes any deference at all to—

[13] ALJs are not bound by LCDs, but are required to afford them "substantial deference." 42 C.F.R. § 405.1062(a). ALJs are not authorized to "set aside or review the validity of an . . . LCD for purposes of a claim appeal." *Id.* § 405.1062(c).

much less is bound by—decisions of lower reviewing bodies addressing different disputes between different parties merely because they pertain to the same device." *Almy*, 679 F.3d at 310. Indeed, ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC second level of review. *See* 42 C.F.R. § 405.968(b) (omitting ALJ decisions among the rulings that bind the QIC). Plaintiffs also agree that ALJ decisions are not precedential. CAR at 55 ("An ALJ's decision to decline to follow an LCD in a particular case has no precedential effect . . . .").

Giving preclusive effect to ALJ decisions is also contrary to the Medicare statute, which provides that the Council must "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B) (emphasis added); *see Porzecanski*, 943 F.3d at 477 ("Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.") (citing 42 C.F.R. §§ 401.109, 405.1130, 405.1048). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ's conclusions. *Almy*, 679 F.3d at 303 (concluding that the Council's obligation to undertake "de novo" review was "incompatible with [plaintiff's] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below").

Because the Medicare regulations specifically designate ALJ decisions as non-binding and non-precedential, and the application of collateral estoppel is contrary to the Medicare statute, collateral estoppel cannot apply here. *See Astoria* at 111–12 (rejecting application of collateral estoppel to a federal statute because applying the principle would render a section of that statute superfluous).

2. Collateral estoppel interferes with the discretion and deference afforded to the Secretary to implement the Medicare Statute.

If ALJ decisions were deemed binding, they would also interfere with the deference and discretion afforded to the Secretary to implement the Medicare statute's "reasonable and necessary" standard for coverage of items and services furnished to program beneficiaries. "[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve "this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process." *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed arguments that interfere with this discretion, holding that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Ringer*, 466 U.S. at 617; *see also Guernsey Mem'l Hosp.*, 514 U.S. at 97 ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate.").

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, have the right to de novo review of any subsequent claims. The application of collateral estoppel, therefore, is fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiffs' view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pl. Br. at 10. Individual adjudication would be

impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. Accordingly, it is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

Here, the Secretary's decision that ALJ decisions are non-binding and non-precedential is expressed in the plain, unambiguous language of the applicable law and regulations. *See Avalon Place Trinity*, DAB No. 2819, at 13 (2017) ("An unappealed ALJ decision [does not set] a precedent binding on ALJs or the Board. When the *Board* has not reviewed the ALJ decision, the *Board* has not issued a decision in that case. Regardless of whether an ALJ decision was appealed to the Board, an ALJ decision is not precedential and does not bind the Board, and is relevant in later cases only to the extent its reasoning is on point and persuasive.") (italics in original), *aff'd*, *Avalon Place Trinity v. HHS*, 761 F. App'x 407 (5th Cir. Mar. 4, 2019). Again, it is undisputed that ALJ decisions "have no precedential effect." CAR at 55. Because giving preclusive effect to ALJ rulings would contravene the Medicare regulations, the Court should decline to apply collateral estoppel here.

While Plaintiffs fails to cite any cases on point,[14] the Fourth, Fifth, Seventh, Ninth, and D.C. Circuits have each rejected similar attempts to bind federal agencies to non-precedential

[14] Plaintiffs' reliance on the unpublished decision in *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005) is misplaced. Pl. Br. at 3. The court found that, under circumstances unique to Social Security disability appeals, an applicant (not the government) was bound by an ALJ's earlier finding concerning the exertion level of the applicant's past work. *Id.* at 546-48. Plaintiffs' additional citation, Pl. Br. at 3, to a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D.

decisions in lower-level administrative appeals. In *Almy*, plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting that "[t]he Secretary's own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported 'policy' in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage." *Id.* at 303 (citing 42 C.F.R. § 405.1062). The Fourth Circuit noted that Congress gave the Secretary discretion to "decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year." *Id.* at 304. Likewise, this Court should reject Plaintiffs' attempt to elevate non-precedential ALJ opinions into binding coverage rules, which would "stultify the administrative process." *Id.* (quoting *Chenery*, 332 U.S. at 202).

The Fourth Circuit noted that other circuits have concluded that "[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently." *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its "well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions." *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, "a definitive and binding statement on behalf of the agency must come from a source with the authority to bind the agency." *Devon*

Cal. 2015). Among other things, unlike the Medicare statute and regulations' prohibition on collateral estoppel here, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration Judge in granting asylum. *Id.* at 1093-94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091-93.

Energy Corp. v. Kempthorne, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g.*, *Freeman v. U.S. Dep't of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) (finding that "unappealed" ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs and noting that the lack of appeal did not "elevate them to the level of a binding final agency action").

The Ninth Circuit explicitly adopted the reasoning in *Almy*, reversing a district court decision that "incorrectly measured agency inconsistency across" ALJ decisions. *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012); *see also County of Los Angeles v. Leavitt*, 521 F.3d 1073, 1079 (9th Cir. 2008) (noting that "intermediary interpretations are not binding on the Secretary, who alone makes policy"). Likewise, the Seventh Circuit recognized that lower-level decisions may conflict and do not bind the Secretary. *Abraham Memorial Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) ("The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS's long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative."); *Homemakers North Shore, Inc. v. Bowen*, 832 F.2d 408, 413 (7th Cir. 1987) ("'The Secretary's position' is the position of the Department as an entity, and the fact that people in the chain of command have expressed divergent views does not diminish the effect of the agency's resolution of those disputes. An inconsistent administrative position means flipflops by the agency over time, rather than reversals within the bureaucratic pyramid."). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) ("[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim

decision made along the way in an agency where the ultimate decision of the agency is controlling.").

In sum, "Congress has delegated broad authority to the Secretary to determine when a device is reasonable and necessary, as well as broad authority to select the procedures used for making that determination. The decisions of local contractors cannot deprive her of that discretion, *any more than the diverse decisions of district courts or courts of appeals throughout the country could bind the Supreme Court*." *Almy*, 679 F.3d at 311 (emphasis added). The doctrine of collateral estoppel cannot transform an ALJ ruling from what is – a decision by an intermediate-level tribunal that is only binding in a single case – to what it is not – an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. Collateral estoppel is contrary to the Medicare Act's presentment and channeling requirements.

Plaintiff's Complaint seeks injunctive relief against the Secretary and a finding that the "Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiffs is a covered benefit." Compl. at 1, 10.[15] In *Porzecanski*, the D.C. Circuit recently held that the Medicare statute prohibits a Medicare beneficiary from obtaining "prospective equitable relief mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations." 943 F.3d at 475.

The facts in *Porzecanksi* are remarkably similar to those in the instant case. Porzecanski suffered from a rare, life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. At the time, there was a dearth of

[15] Plaintiffs' motion does not mention the request for equitable relief contained in the Complaint, and thus abandons it.

scientific testing supporting the product for plaintiff's symptoms; nonetheless, during the course of plaintiff's treatment, the product came to be considered the best available treatment. *Id.* After beginning treatment, Porzecanski remained symptom-free and his physicians recommended that he continue the monthly treatment indefinitely. *Id.* at 476-77. After one of his claims was denied at the ALJ level and the Council did not render a decision within the required time frame, plaintiff filed in federal court. *Id.* at 477. While the federal case was pending, plaintiff continued to submit monthly Medicare claims, which were approved by a QIC or ALJ. *Id.* On appeal of his denied claim, plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that plaintiff could not "satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and section 405(g) requires appeals from "decision[s]" of the Secretary, the presentment requirement could not be met: "[T]he Secretary has not decided [plaintiff's] future claims because – to state the obvious – none has been submitted." *Id.*

The court also rejected plaintiff's request to *preclude* the Secretary from concluding that the claims on appeal were not covered by Medicare and were not medically necessary – the *identical* relief that Plaintiffs seek here. *Id.* at 482 (finding plaintiff's "strained position" to be "at odds with Supreme Court precedent."). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, "the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was 'reasonable and necessary' under the Medicare Act." *Id.* (citing 466 U.S.

at 620-21). Although the patient sought equitable relief, it was "essentially one requesting the payment of benefits." *Id.* (quoting 466 U.S. at 620). Any claim seeking to establish a right of future payments constitutes a "claim arising under" the Medicare Act. *Id.* (citing 466 U.S. at 621). Likewise, in *Illinois Council*, the Court again declared that a "claim for future benefits is a § 405(h) claim" and that "all aspects" of any future claim "must be channeled through the administrative process." *Id.* (citing 529 U.S. at 12).

The D.C. Circuit thus concluded, "*Ringer* and *Illinois Council* directly foreclose [plaintiff's] attempt to recast the requested relief as anything other than a claim for future benefits." *Id.* at 483. Likewise, Plaintiffs' assertion that the Secretary is estopped from denying their future claims for TTFT treatment "runs headlong into the Supreme Court's instruction that 'all aspects' of a claim be first channeled through the agency." *Id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiffs cannot leverage a favorable ALJ decision to estop the Secretary from denying "future claims for the same reasons." *Id.* at 483-84.

4. Collateral estoppel is contrary to the Appropriations Clause of the U.S. Constitution.

The Appropriations Clause of the Constitution, Art. I, § 9, cl. 7, provides that: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." In *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990), the Supreme Court held that the government, despite the erroneous oral and written representations of a federal employee, was not equitably estopped from determining that a claimant who exceeded the statutory limit on earnings was ineligible for disability benefits. The Supreme Court concluded:

> Whether there are any extreme circumstances that might support estoppel in a case not involving payment from the Treasury is a matter we need not address. As for monetary claims, it is enough to say that this Court has never upheld an assertion of estoppel against the Government by a claimant seeking public funds. In this context, there can be no estoppel, for courts cannot estop the Constitution.

Id. at 434. *See also Genesis Health Ventures, Inc. v. Sebelius*, 798 F. Supp. 2d 170, 183 (D.D.C. 2011) ("[N]either the Supreme Court nor our Court of Appeals has ever upheld "an estoppel claim against the Government 'for the payment of money.'") (citing *Richmond*, 496 U.S. at 427).

Courts have applied the holding in *Richmond* to the Medicare context. In *Monongahela Valley Hosp., Inc. v. Sullivan*, 945 F.2d 576 (3d Cir. 1991), the Third Circuit held that *Richmond* foreclosed a Medicare provider's estoppel claim against the Secretary for additional Medicare reimbursement. *Id.* at 588-89. Likewise, in *Downtown Medical Center/Comprehensive Health Care Clinic v. Bowen*, the Tenth Circuit declined to estop the Secretary and a private insurer, which processed Medicare claims on the Secretary's behalf, from denying the plaintiff's reimbursement claim. 944 F.2d 756, 771 (10th Cir. 1991). *See also Almy*, 679 F.3d at 312 ("It is the Secretary, not the courts, who bears the responsibility for the disbursement of billions of dollars of public money under the Medicare system.").

The same reasoning applies to Plaintiffs' assertion of collateral estoppel. Plaintiffs seek to estop the Secretary from denying their claims payment from the Medicare Trust Fund. Of course, no appropriation of Congress entitles Plaintiffs to future payments from the Medicare Trust Fund. Because Plaintiffs seek to draw money from the Treasury on equitable grounds, the Court must deny their assertion of collateral estoppel.

5. The elements of collateral estoppel are not present here.

The Third Circuit has identified four required elements for the application of collateral estoppel: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (internal quotations omitted). The

Third Circuit considers whether the party being precluded "had a full and fair opportunity to litigate the issue in question in the prior action, . . . and whether the issue was determined by a final and valid judgment." *Id.* (internal quotation marks and citations omitted). Third Circuit courts also require that the adjudicator at the prior proceeding confronted and decided the question, not merely remarked on it in dicta. *See Khalil v. Rohm & Haas Co.*, 2008 WL 383322, at *14 (E.D. Pa. Feb. 11, 2008) (citing *Hawksbill Sea Turtle v. Fed. Emergency Mgmt. Agency*, 126 F.3d 461, 465 (3d Cir. 1997)).).

As noted above, collateral estoppel cannot apply as to Plaintiff Lewis, because the unfavorable decision on appeal here (dated May 30, 2019) *predates* his favorable ALJ decision (dated October 24, 2019). *See supra* § IV.A. Nor does collateral estoppel apply as to either Plaintiff, because the first, second, and fourth elements of collateral estoppel are not met.

First, the issues decided in Plaintiffs' claim appeals were different, because they each concerned whether TTFT treatment was covered under Medicare for a *specific period in time*. *See* Pl. Br. at 5 ("Each claim for Medicare coverage concerns only the one to three months at issue for that claim."). Notably, both the ALJ who denied Oxenberg's treatment and the ALJ who approved her treatment limited their "Conclusions of Law" to specific coverage dates. *See* Ex. A to Pl. Br. at 6 (6/3/19 Favorable Decision) (approving coverage for dates of service from July-October 2018); CAR at 110 (9/5/19 Unfavorable Decision) (denying coverage for dates of service from April-June 2018). Likewise, the ALJs who decided Lewis' claims limited their "Conclusions of Law" to specific coverage dates. *See* CAR at 840 (5/3/19 Unfavorable Decision); Ex. F to Pl. Br. at 4 (10/24/19 Favorable Decision). Because the favorable ALJ decisions did not adjudicate whether Medicare coverage existed for any other claims, much less the claims simultaneously on appeal before another ALJ, the first element of collateral estoppel

is not present.[16] *See, e.g.*, *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods).

Furthermore, the issues decided in Plaintiffs' favorable and unfavorable ALJ decisions were substantially different. In the favorable ruling for Oxenberg, the ALJ declined to apply the LCD without conducting a review of its validity. *See* Ex. A. to Pl. Br. at 5-6. In the unfavorable ruling, however, Oxenberg improperly asked the ALJ to set aside the LCD. CAR at 108-110. Accordingly, the ALJ denied her claim on the basis that a claim appeal is not the proper forum for challenging the validity of the LCD. *Id.*; 42 C.F.R. § 405.1062(c) (an ALJ does not have authority to "set aside" or "review the validity" of an LCD in a claim appeal). Likewise, Lewis' unfavorable decision stemmed from his improper request to set aside the LCD (CAR at 838-39), while a subsequent decision approved his claim without discussing the LCD's validity (Ex. F. to Pl. Br. at 3-4). Several courts have noted that the regulations forbid ALJs from setting aside an LCD in the context of a claim appeal.[17]

Plaintiffs, however, were not without recourse and could have challenged the LCD or petitioned CMS for a National Coverage Determination under entirely separate channels of review. *See* 42 U.S.C. § 1395y(l) (describing the process of requesting an NCD); 42 C.F.R. §

---

[16] Even if the favorable decision had addressed Medicare coverage for other time periods – which it did not – that discussion would be mere dicta and insufficient for the application of collateral estoppel. *See Khalil*, 2008 WL 383322, at *14.

[17] *See Odell v. Azar*, 344 F. Supp. 3d 1192, 1198, 1202 (D. Nev. 2018) (noting that plaintiff "can appeal an individual claim as a supplier, but an ALJ or the Council cannot review the validity of an LCD for purposes of a claim appeal."); *Medicomp, Inc. v. HHS*, 2016 WL 901282, at *6-7 (M.D. Fla. Mar. 3, 2016) (finding that plaintiff's presentation of clinical or scientific evidence at the ALJ level constituted a challenge to the LCD's validity and noting that ALJs do not have authority to set aside an LCD in a claim appeal).

426.425 (only by raising an LCD challenge can an aggrieved party "state why the LCD is not valid"); *Porzecanksi*, 943 F.3d at 486 ("There is a distinct path provided for beneficiaries to secure broader coverage determinations and [plaintiff] cannot circumvent those procedures"), 486 n.12 (explaining the distinct channels for challenging an LCD versus filing a claim appeal).[18] Because the unfavorable ruling was based upon Plaintiffs' improper challenge to the LCD in a claim appeal – an issue that was not even presented, much less decided, in the favorable decision – collateral estoppel does not apply.

Second, the favorable ALJ ruling did not involve any litigation as to whether Medicare coverage existed for any other time periods. Indeed, the Secretary was not a party to Plaintiffs' favorably decided appeals, which, by itself, militates against the application of collateral estoppel. Exs. A-C, F to Pl. Br.; *see, e.g., Weinstein v. Islamic Rep. of Iran*, 175 F. Supp. 2d 13, 21 (D.D.C. 2001) (declining to apply collateral estoppel where defendants failed to make an appearance).

As to the fourth element, the Secretary has a limited opportunity to litigate Medicare coverage appeals. Indeed, the Secretary has no opportunity to participate during the first (redetermination) and second (QIC) levels of the administrative appeal process. *See* 42 C.F.R. §§ 405.948, 405.968. It would obviously be improper to find that the Secretary had a "full and fair" opportunity to participate under those circumstances. *See Genesis Health*, 798 F. Supp. 2d at 182 ("[I]f an intermediary finds coverage and pays a claim, there is never an administrative

---

[18] A beneficiary may challenge an LCD before receiving an item or service or after the LCD has been applied, resulting in a coverage denial. 68 Fed. Reg. 63692, 63693-94 (Nov. 7, 2003). "[A] successful challenge would permit the individual to have his or her specific claim reviewed without reference to the challenged policy." *Id.* In other words, Plaintiffs had the opportunity to seek coverage for their claims by challenging the LCD, but opted instead to pursue the narrower relief available in a claim appeal.

appeal, and the Secretary would have no knowledge of the intermediary's decision nor opportunity to review those actions.").

The Secretary has a limited opportunity to litigate ALJ appeals. If the beneficiary is unrepresented, then the Secretary cannot be a party to the hearing, and thus has no opportunity to litigate. 42 C.F.R. § 405.1012(a). Furthermore, if the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings, the proceedings simply move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate hundreds of thousands of appeals annually. 42 C.F.R. §§ 405.1010(a), 405.1012; *see supra* n.2.

If the Secretary does not become a party to an ALJ hearing, it cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Because the Secretary's opportunity to appeal was also extremely limited, it did not have the full and fair opportunity to litigate. *See DePolo v. Bd. of Supervisors of Tredyffrin Twp.*, 835 F.3d 381, 387 (3d Cir. 2016) ("We have explained that 'in determining whether a litigant has been given a 'full and fair' opportunity to litigate a claim, we must take into account the possibility of appellate review' because a full and fair opportunity to litigate 'includes the possibility of a chain of appellate review.'") (quoting *Crossroads Cogeneration Corp. v. Orange & Rockland Utils., Inc.*, 159 F.3d 129, 137 (3d Cir. 1998)).

6. It would be unfair to apply collateral estoppel offensively against the Secretary.

The Supreme Court has granted district courts "broad discretion" to determine when a plaintiff who has met the requisites for the application of collateral estoppel may employ that

doctrine offensively. *See Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979). The Court explained:

> If a defendant in the first action is sued for small or nominal damages, he [or she] may have little incentive to defend vigorously, particularly if future suits are not foreseeable. . . . [If] the application of offensive estoppel would be unfair to a defendant, a trial judge should not allow the use of offensive collateral estoppel.

Id. at 330–31 (citations omitted). Under Third Circuit law, a "finding of fairness to the defendant is thus a necessary premise to the application of offensive collateral estoppel." *Raytech Corp. v. White*, 54 F.3d 187, 195 (3d Cir. 1995).

The Supreme Court has never upheld the application of offensive collateral estoppel against the United States, and "it is well-settled that the Government may not be estopped on the same terms as any other litigant." *Community Health Servs.*, 467 U.S. at 60. The seminal case on point is *United States v. Mendoza*, 464 U.S. 154 (1984). In *Mendoza*, the Court held that the "United States may not be collaterally estopped on an issue . . . adjudicated against it in an earlier lawsuit brought by a different party." *Id.* at 155. The Court distinguished *Parklane Hosiery*, 439 U.S. 322 (1979), holding that "nonmutual collateral estoppel is not be extended to the United States." *Id.* at 159. The Court's decision stemmed from its recognition that "'the Government is not in a position identical to that of a private litigant,' both because of the geographic breadth of government litigation and also, most importantly, because of the nature of the issues the government litigates." *Id.* (quoting *INS v. Hibi*, 414 U.S. 5, 8 (1973) (per curiam)).

The Court noted that the government is "party to a far greater number of cases on a nationwide basis than even the most litigious private entity." *Id.* The government is likely to be involved in lawsuits against different parties that involve the same legal issues – issues that are frequently of substantial public importance. *Id.* at 160. Accordingly, allowing non-mutual

collateral estoppel "would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue." *Id.* Rather than receiving the benefit of several courts of appeal decisions, the Supreme Court could only review one final decision before granting certiorari. *Id.*

In addition, the Court approved of the Solicitor General's discretion when determining whether to appeal. Unlike a private litigant, the Solicitor General "considers a variety of factors, such as the limited resources of the government and the crowded dockets of the courts, before authorizing an appeal." *Id.* at 161. On the other hand, if non-mutual estoppel applied against the Government, the Solicitor General would have to "abandon those prudential concerns and . . . appeal every adverse decision in order to avoid foreclosing further review." *Id.* The Court concluded that "[t]he conduct of government litigation in the courts of the United States is sufficiently different from the conduct of private civil litigation in those courts so that what might otherwise be economy interests underlying a broad application of collateral estoppel are outweighed by the constraints which peculiarly affect the government." *Id.* at 162-63; *see also Jones v. Ashcroft*, 321 F. Supp. 2d 1, 6 (D.C. Cir. 2004) (noting that "a plaintiff generally may not apply offensive collateral estoppel against the government.").

The policy reasons against collaterally estopping the United States apply with particular force here. As in *Parklane* and *Mendoza*, it would not be practicable for the Secretary to defend himself in the over 400,000 ALJ appeals filed each year. Accordingly, the Secretary generally devotes his resources to administering payment of Medicare claims. Nor would the Secretary have any reason to believe that a favorable ALJ ruling could have preclusive effect in future claims, because that outcome would be contrary to the Medicare statute and regulations, Supreme Court precedent, and a number of circuit-level decisions. *See supra* §§ IV.B.1-2. The

Medicare appeals process explicitly permits ALJs to reach varying conclusions, and gives the Council discretion to impose uniformity by issuing precedential decisions. As with federal courts, allowing conflicting decisions to percolate up to a higher level improves the decision-making process. *See Mendoza*, 464 U.S. at 160. Finding that an ALJ decision deprives the Secretary of discretion when to make a final determination would be akin to finding that a district court decision could bind the Supreme Court. *See Almy*, 679 F.3d at 310.

The Medicare appeals process is particularly unsuited to the application of collateral estoppel. In *Porzecanksi*, the D.C. Circuit held that "stretch[ing] the outcome of a single claim dispute to foreclose a contrary decision in any future determination . . . is at odds with the Medicare regime. . . . Medical science changes. An accepted practice may be obsolete in a few years. Ordering HHS to cover [plaintiff's] treatments indefinitely can hardly be necessary to effectuate the district court's judgment regarding one treatment at a particular point in time." 943 F.3d at 486. Likewise, the Fourth Circuit concluded that plaintiff's "proposed expansion of what constitutes binding agency precedent would severely constrict the undisputed delegated authority of the Secretary to administer the Medicare system." *Almy*, 749 F.3d at 310. The court continued:

> [Plaintiff] seeks to impose massive resource costs on the Secretary, requiring her to reverse any decision at a lower level of adjudication either through promulgation of an NCD or through [Council] review lest that lower decision become precedent that precludes a different considered result in future cases before the [Council]. As the Secretary notes, there were 970 million Medicare Part B claims in 2008 alone, and the Secretary rarely participates in the lower level adjudications of those claim determinations. . . . The Secretary has simply not seen fit to invoke her final authority in every case in which there is an argument over whether the evidence adequately supports a finding that a device was "reasonable and necessary."

Id. at 311 (citations omitted). Accordingly, even assuming that collateral estoppel were legally supportable – which it is not – as a matter of policy, the doctrine of collateral estoppel has no place in Medicare claims appeals and would impose massive costs upon this critical national program and undermine its mission to support the health of the tens of millions of Americans who are Medicare beneficiaries.

The fairness element is also lacking because collateral estoppel could only run against the Secretary – not against the beneficiary. While denial of a beneficiary's claim has no effect on any future claim, under Plaintiffs' proposal, a single claim approval would forever estop the Secretary from denying future claims. Contrary to decades of Supreme Court precedent, the United States would be *more* susceptible to collateral estoppel than would private litigants. Because the application of collateral estoppel would be fundamentally unfair to the Secretary, it should not be applied here.

7. Even if collateral estoppel applied, it would have no force after the new LCD became effective on September 1, 2019.

Even if collateral estoppel applied here, which it surely does not, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when "'controlling facts or legal principles have changed significantly since the [prior] judgment.'" *Karns v. Shanahan*, 879 F.3d 504, 514 (3d Cir. 2018) (alteration in original) (quoting *Montana*, 440 U.S. at 155. Here, there is no doubt that there was a significant change between the old LCD, which categorically denied coverage for TTFT treatment, and the new LCD, which allowed coverage of TTFT under certain circumstances. Accordingly, if Plaintiff were to prevail on collateral estoppel, the only decision that might be estopped would be the September 5, 2019 decision denying Oxenberg's treatment. Further preclusive or injunctive

relief would not be warranted, because the new LCD has already been in place for over six months.

Along the same lines, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, *indefinitely* into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (*e.g.*, when a patient suffers serious side effects). In this case, there is no evidence that the facts supporting Plaintiffs' claims for coverage in 2018 are identical to the facts supporting their claims for coverage in 2020. Even if their medical history remained unchanged for two years, it would be pure speculation to assert that the facts would remain unchanged for any claim they might file in the future. For example, if Plaintiffs filed claims for coverage, but the evidence showed that they were not actually using the device, Medicare should not be required to approve their claims. *See* CAR at 136 (2019 LCD requires that a beneficiary "use TTFT for an average of 18 hours per day").

Because the controlling facts and law have changed, applying collateral estoppel would have zero benefit for Plaintiffs, who are not financially responsible for the claims on appeal. Meanwhile, a finding that favorable ALJ decisions have preclusive effect would have widespread, negative ramifications for the Medicare program, and the many million Americans it serves. Because collateral estoppel is fundamentally inconsistent with the Medicare Program, the Court should grant summary judgment for the Secretary.

V. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his cross-motion for summary judgment and deny Plaintiffs' motion for summary judgment.

Respectfully submitted,

WILLIAM M. McSWAIN
United States Attorney

/s/ Susan R. Becker
for Gregory B. David
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

/s/ Eric S. Wolfish
ERIC S. WOLFISH
Special Assistant United States Attorney/
Assistant Regional Counsel, HHS
Eric.Wolfish@hhs.gov

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
Tel: 215-861-8335
Fax: 215-861-8618
Matthew.Howatt@usdoj.gov

Dated: April 20, 2020

CERTIFICATE OF SERVICE

I hereby certify that on this day, I caused a true and correct copy of the foregoing cross-motion for summary judgment to be served on all counsel of record via the Court's CM/ECF system.

/s/ Matthew E. K. Howatt
MATTHEW E. K. HOWATT
Assistant United States Attorney

Dated: April 20, 2020